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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,659	10/25/2001	Pamela A. Kramer	ACS-54306(22571)	6167

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EXAMINER	
WOO, JULIAN W	
ART UNIT	**PAPER NUMBER**
3731	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/032,659	KRAMER ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,14-16,22-24,26-29 and 41-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 14-16, 22-24, 26-29, and 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Doore et al. (4,012,795). Doore et al. disclose, at least in figure 1 and in col. 3, lines 20-37; a medical device (1) including a metal alloy substrate (aluminum oxide) having an average grain size in the range of one to ten microns.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-9, 14-16, 22-24, 26-29, 41-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Reimann et al. (3,723,193). Frantzen discloses the invention substantially as claimed. Frantzen discloses, at least in figures 1 and 5 and in col. 8, lines 30-63; a medical device or an intravasclular stent comprising a metal alloy substrate that is stainless steel. Frantzen discloses that the stent includes a plurality of interconnected cylindrical rings or a plurality of struts or elongate elements (e.g. 20 or 120) and straight links (e.g., 50 or 150) or undulating links (e.g., 180). However, Frantzen does not disclose that the substrate has an average grain size in the range of one to ten microns, nor does Frantzen disclose that the stainless steel is 316L stainless steel, that the number of grains across a strut thickness is in the range of five to fifteen, that the average number of grains across an element thickness is more than six, that the average grain size of the 316L stainless steel is in the range of three to eight microns or about five microns. Frantzen also do not disclose a substrate that is cobalt-chromium alloy, nickel-titanium alloy, platinum-iridium alloy, and titanium based alloy. Reimann et al. teach, in col. 5, line 10 to col. 6, line 10, a device comprising 316L stainless steel having an average grain size in the range of one to ten microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Reimann et al., to form the substrate of the device of Frantzen out of fine-grained 316L stainless steel. Such a material would provide improved ductility for the medical device or stent, so that it would not readily break upon expansion. Also, it would have been a matter of obvious design choice to dimension the strut thickness of element thickness (i.e., the number of

grains) and the average grain size as claimed, since such modifications would have involved mere changes in the size of components. A change in size is generally recognized as being with the level of ordinary skill in the art.

Riemann et al. also teach, in col. 2, lines 26-66, that various metal alloys (e.g., alloy steels and aluminum alloys) may be prepared such that they have a structure of fine grains. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the substrate of the device of Frantzen out of the other metal alloys as claimed, since it has been held to be within the general skill of a worker in the art to select a known, biocompatible material on the basis of its suitability for the intended use as a matter of obvious design choice.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Reimann et al. (3,723,193) as applied to claim 1 above, and further in view of Kumar et al. (5,171,379). Frantzen in view of Reimann et al. discloses the invention substantially as claimed, but does not specify a substrate that is a tantalum-based alloy. Kumar et al. teach a fine-grained tantalum-based alloy as a substrate for various devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kumar et al., to include a tantalum-based alloy as a substrate material for the medical device of Frantzen in view of Reimann et al. Such a material is biocompatible and ductile, and it would be effective for use in a medical device that is expandable.

6. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen (5,843,175) in view of Zhu et al. (6,399,215). Frantzen discloses the invention

substantially as claimed. Frantzen discloses a stent comprising a metal substrate that can be "heated and then quenched as desired to produce a grain size consistent with the amount of flexibility and hardness which could give the stent the strength characteristics desired and yet avoid excessive brittleness" (See col. 15, lines 3-11). However, Frantzen does not disclose that the substrate has an average grain size in the range of one to ten microns and consists of titanium or tantalum. Zhu et al. teach, at least in col. 3, lines 29-39; ultrafine-grained titanum for use in medical implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Zhu et al., to form the substrate of Frantzen's stent out of ultrafine-grained titanium. Such a material is biocompatible, strong, ductile, and free of toxic alloy elements, so it would be effective for use in the implantable and expandable medical device that is Frantzen's stent. However, Zhu et al. also do not disclose a device substrate that is in the range of one to ten microns.

Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the substrate of the device of Frantzen or Frantzen in view of Zhu et al. so that it has an average grain size in the range of one to ten microns; since it has been held that where the general conditions of a claim (e.g., grain size of a substrate) are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Response to Amendment

7. Applicant's arguments with respect to claims 1, 3-10, 14-16, 22-24, 26-29, and 41-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

July 5, 2007